

(1) “Do not give to children under 12 years of age.”

(2) “If sleeplessness persists continuously for more than 2 weeks, consult your doctor. Insomnia may be a symptom of serious underlying medical illness.”

(3) “Do not take this product, unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland.”

(4) “Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor.”

(d) *Directions.* The labeling of the product contains the following information under the heading “Directions”:

(1) *For products containing diphenhydramine hydrochloride identified in §338.10(a).* Adults and children 12 years of age and over: Oral dosage is 50 milligrams at bedtime if needed, or as directed by a doctor.

(2) *For products containing diphenhydramine citrate identified in §338.10(b).* Adults and children 12 years of age and over: Oral dosage is 76 milligrams at bedtime if needed, or as directed by a doctor.

(e) The word “physician” may be substituted for the word “doctor” in any of the labeling statements in this section.

[54 FR 6826, Feb. 14, 1989, as amended at 59 FR 16983, Apr. 11, 1994]

EFFECTIVE DATE NOTE: At 67 FR 72559, Dec. 6, 2002, §338.50 was amended by adding paragraph (c)(5), effective Dec. 8, 2003. For the convenience of the user, the added text is set forth as follows:

§338.50 Labeling of nighttime sleep-aid drug products.

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(c) * * *

(5) “Do not use [bullet]¹ with any other product containing diphenhydramine, even one used on skin”.

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¹ See §201.66(b)(4) of this chapter for definition of bullet symbol.

PART 340—STIMULANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

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AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 53 FR 6105, Feb. 29, 1988, unless otherwise noted.

Subpart A—General Provisions

§340.1 Scope.

(a) An over-the-counter stimulant drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this part and each of the general conditions established in §330.1.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§340.3 Definition.

As used in this part:

Stimulant. A drug which helps restore mental alertness or wakefulness during fatigue or drowsiness.

Subpart B—Active Ingredient

§340.10 Stimulant active ingredient.

The active ingredient of the product consists of caffeine when used within the dosage limits established in §340.50(d).

Subpart C—Labeling

§340.50 Labeling of stimulant drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies